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VS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/934,367	09/19/97	NEEDLEMAN	P MON-103.0-(6)
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HM22/0913

WELSH AND KATZ LTD
120 SOUTH RIVERSIDE PLAZA
22ND FLOOR
CHICAGO IL 60606

EXAMINER

EYLER, Y

ART UNIT

PAPER NUMBER

1642

12

DATE MAILED:

09/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/934,367

Applicant(s)

Needleman et al.

Examiner

Yvonne Eyer

Group Art Unit

1642

☒ Responsive to communication(s) filed on Jun 21, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-11 and 15-31 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 and 15-31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

Claims 1-11 and 15-31 are pending in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

1. The rejection of Claims 1-21 under 35 U.S.C. 103(a) as being unpatentable over Rittershaus et al. (WO 9634888) in view of Felgner et al. (US.# 5,580,859) and further in view of Swenson et al. (J. Biol. Chem.) is withdrawn in light of the Declarations submitted 6/21/99.

Claim Rejections Maintained and New Grounds of Rejection:

2. Claims 22, 23, 27, 28, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22, 23, 28 and 31 recite sequences selected from a group of numbers but do not indicate that these are SEQ ID NOS.

Claim 27 depends from claim 26 but recites "said encoded rabbit CETP" for which there is no antecedent basis in claim 26 which refers to monkey CETP.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-11, 15, 16, and 22-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 9, 11 and 15-28 of copending Application No. 08/785,977 and over claims 18-21 and 38-42 of copending Application No. 08/788882 in view of Felgner et al. (U.S.# 5,580,859).

Claims 4, 9, 11 and 15-28 of 08/785,997 are drawn to a process of increasing HDL cholesterol and to generating antibodies to CETP by inoculation with an immunogen of CETP covalently linked to an immunogenic carrier.

Claims 18-21 and 38-42 of 08/788882 are drawn to the immunogen, CETP covalently linked to an immunogenic carrier.

08/785,997 and 08/788882 differ in that the process and the immunogen are polypeptide, not DNA encoding the polypeptide.

Felgner et al. that there are several recognized advantages to eliciting peptide specific antibodies by direct administration of exogenous DNA (which are then expressed) rather than by

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administration of the peptide itself. Advantages include avoidance of anaphylactic reaction, sustained exposure, etc.

It would have been *prima facie* obvious to one of ordinary skill in the art to modify the process and inoculum of 08/785,997 and 08/788882 to directly inject the DNA with a reasonable expectation of success given the known advantages of doing so as taught by Felgner et al.

This is a provisional obviousness-type double patenting rejection.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 630pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Yvonne Eyler, Ph.D.
Primary Examiner
September 12, 1999